DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 18, 2017

C.R. Bard, Inc.
Henry Boland
Associate Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K081288
Trade/Device Name: Aspira* Peritoneal Drainage System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: PNG
Dated: July 1, 2008
Received: July 2, 2008

Dear Henry Boland:

This letter corrects our substantially equivalent letter of July 18, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K081288

Device Name: Aspira* Peritoneal Drainage System

Indications for Use:

The **Aspira*** Peritoneal Drainage System is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

The **Aspira*** Drainage Bag is indicated for use only with the **Aspira*** Drainage Catheter for intermittent drainage.

The **Aspira*** Dressing Kit is indicated for dressing of a catheter and exit site.

The **Aspira*** Luer Adapter is intended to provide access to the **Aspira*** Drainage Catheter. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe or other appropriate method.

The **Aspira*** Valve Assembly attaches to the **Aspira*** Drainage Catheter. The **Aspira*** Repair Kit is for the repair of the **Aspira*** Drainage Catheter and replacement of the **Aspira*** Valve Assembly.

*Aspira is a trademark and/or registered trademark of C. R. Bard, Inc. or an affiliate.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081288

Section 5
510(k) Summary
21 CFR 807.92(a)

JUL 18 2008

5.1 General Information

Submitter Name:	**Bard Access Systems, Inc. (BAS)** [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	605 North 5600 West Salt Lake City, Utah 84116
Telephone Number:	(801) 595-0700 ext. 5428
Fax Number:	(801) 595-5425
Contact Person:	Henry Boland
Date of Preparation:	May 6, 2008
Registration Numbers:	
Bard Access Systems:	3006260740
C. R. Bard:	2212754

5.2 Subject Device Information

Device Name:	**Aspira*** Peritoneal Drainage System
Trade Name:	**Aspira***
Common/Usual Name:	Catheter, peritoneal, long-term indwelling
Classification Name:	Peritoneal dialysis system and accessories 21 CFR 876.5630, Class II FJS - Peritoneal dialysis system and accessories
Classification Panel:	Gastroenterology/Urology

5.3 Predicate Device Information

Device Name:	**Cardinal Health** (formerly **Denver Biomedical**) **PLEURX™** Peritoneal Catheter Kit and **PLEURX™** Drainage Kit
Trade Name:	**PLEURX™**
Common/Usual Name:	Catheter, peritoneal, long-term indwelling
Classification Name:	Peritoneal dialysis system and accessories 21 CFR 876.5630 – Class II FJS - Peritoneal dialysis system and accessories
Classification Panel:	Gastroenterology/Urology
510(k) Clearance:	K051711, concurrence date November 15, 2005

5.4 Intended Use

The **Aspira*** Peritoneal Drainage System is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

5.5 Indications for Use

The **Aspira*** Peritoneal Drainage System is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

The **Aspira*** Drainage Bag is indicated for use only with the **Aspira*** Drainage Catheter for intermittent drainage.

The **Aspira*** Dressing Kit is indicated for dressing of a catheter and exit site.

The **Aspira*** Luer Adapter is intended to provide access to the **Aspira*** Drainage Catheter. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe or other appropriate method.

The **Aspira*** Valve Assembly attaches to the **Aspira*** Drainage Catheter. The **Aspira*** Repair Kit is for the repair of the **Aspira*** Drainage Catheter and replacement of the **Aspira*** Valve Assembly.

5.6 Device Description

The **Aspira*** Peritoneal Drainage System is designed for long-term intermittent drainage of recurrent and symptomatic malignant ascites. The **Aspira*** Peritoneal Drainage System provides patients with a convenient method to relieve malignant ascites symptoms at home. The primary components of the system are the **Aspira*** Peritoneal Drainage Catheter and the **Aspira*** Drainage Bag.

The **Aspira*** Peritoneal Drainage Catheter is a long-term indwelling silicone catheter used to drain accumulated fluid from the peritoneal cavity to relieve symptoms associated with malignant ascites. The fenestrated catheter is placed in the patient's abdominal cavity enabling the patient or caregiver to perform intermittent drainage of their malignant ascites at home.

The **Aspira*** Drainage Bag is used to collect peritoneal fluid by gravity. The drainage bag attaches to the placed catheter and is activated using an in-line silicone pump.

The **Aspira*** Luer Adapter is designed to access the **Aspira*** Drainage Catheter. The luer adapter is connected to wall suction or a syringe to perform intermittent drainage or catheter maintenance.

The **Aspira*** Valve assembly attaches to the proximal end of the **Aspira*** Drainage Catheter to prevent fluid or air exchange through the catheter when not in use.

5.7 Technological Comparison to Predicate Device

The technological characteristics of the **Aspira*** Peritoneal Drainage System is substantially equivalent to the predicate device, **Denver PLEURX™** Peritoneal Catheter Kit and **PLEURX™** Drainage Kit, in terms of intended use, application, user population, basic design, performance and labeling.

* Bard and Aspira are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.